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(71) Applicant: Acandis GmbH & Co. KG
76327 Pfinztal (DE)

(72) Inventors:
- The inventor has agreed to waive his entitlement to designation.

(74) Representative: Meissner, Bolte & Partner
Anwaltssozietät GbR
Postfach 86 06 24
81633 München (DE)

(54) Damping method and device

(57) A damping and shock absorbing method and apparatus for permanent or non-permanent use in the human body consists out of a shape memory alloy material which is cycled through the stress-strain hysteresis to dissipate energy for an effective damping. A sufficiently high pre-stress is applied to the damping element(s) to ensure that the damping working range is within the supererlastic cycle. The damping apparatus can be designed to work in tension or compression or - by combination of compression and tension elements - both in tension and compression. Moreover, damping elements from a shape memory alloy can be designed to work also in flexion and extension as well in rotation. The damping apparatus can be designed to have a stroke and force suitable for use in the human body by the design, the structure and the chemical composition of the shape memory alloy and their pre-set properties, such as plateau stresses and transformation temperature. Since plateau stresses of the superelastic cycle depend on the ambient temperature, the force of damping elements can also be changed in-situ by changing the temperature of the damping elements. The damping elements out of a shape memory alloy can be combined with elastic elements out of other materials to achieve stress-strain behaviour more suitable for use in the individual human body.

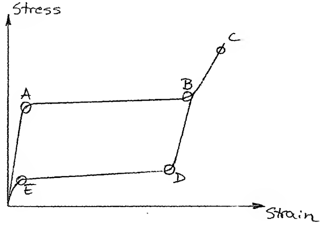

Fig. 1

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Description

Background of the Invention

1. Field of the Invention

[0001] The invention relates to a method and apparatus to passively damp shocks in the human body. More particular the invention relates to a spinal stabilization device which absorbs shocks to the elements of the spinal column by dissipating energy.

2. Description of the Prior Art

[0002] Back pain is one of the most widespread deceases in modern societies. After all conservative treatment (non-invasive) options such as medication, physical therapy, chiropractic or osteopathic manipulations and braces are exhausted patients usually undergo surgical interventions such as laminectomy, discsectomy and finally fusion.

[0003] A spinal fusion surgery is designed to stop the motion at a painful vertebral segment, which in turn should decrease pain generated from the joint. New treatment options, usually called *Non-Fusion Technologies or motion preservation devices* refer to implants which seek to preserve motion while stabilizing vertebra and relieving pain. There are dynamic stabilization devices (interspinous spacers or pedicle screw based), nucleus augmentation/replacement, facet replacement, annulus repair or total disc replacement.

[0004] Dynamic stabilization devices must be flexible in order to allow the spine a normal physiological motion. Thereby it is essential that adjacent levels of the treated segment are not adversely affected by the motion preservation device. Since today, spinal implants - if at all - absorb shocks only elastically (hence affecting adjacent levels) there is a need for true shock absorbing by energy dissipation in motion preservation devices.

[0005] Dynamic stabilization devices are designed to provide a certain resistance to the motion of the injured or damaged spine. Often a non-linear resistance over the range of motion in flexion/extension and tension/compression as well as rotation is desirable. Solutions today are based on complex constructions often containing different materials. Hence there is a need for simple devices build from a biocompatible material which inherently offers different force-deflection characteristics over their range of strain.

[0006] The present invention provides such a method and apparatus for shock absorption in the spinal column in general and device for dynamic stabilization in the spine in general.

Summary of the Invention

[0007] Passive damping or shock absorption is achieved by cycling one or more damping elements build from a shape memory alloy through it's stress-strain hysteresis. Energy is dissipated during the transformation of the microstructure of the material upon loading and unloading in the stress plateaus. Since the phase transformation is fully reversible even at high cycling numbers the principle is used to build damping devices in the human body. The shape memory effect has been proven for a number of metallic materials, including CuZnAl, CuAlNi, FeMgSi, FeNiCoTi and NiTi. However, until today only NiTi containing about 50.8 at% Ni, commonly referred as Nitinol, has reached a widespread use as implant material. Without limiting the scope of this invention which includes shape memory alloys in general, we will refer in the following only to shape memory alloys based on Nickel Titanium.

[0008] Furthermore a NiTi based shape memory alloy phase a stress-strain behaviour different from other metallic implant materials: On loading the material exhibits a high stiffness for small strain levels due to the elastic deformation of the austenitic phase, followed by a reduced stiffness for intermediate strain levels (loading/unloading plateau) and and finally a large stiffness at large strain levels (elastic deformation of the martensitic phase). This provides an ideal centring force for a dynamic stabilization device with an increased resistance in the central zone of the stabilizer (elastic deformation of the Austenite), much less resistance beyond the central zone of the stabilizer (loading stress plateau) and a high resistance at the end of the range of motion (elastic deformation of the Martensite).

[0009] The phenomenon of the stress-strain hysteresis of a NiTi based shape memory alloy is used to construct a dynamic spinal stabilization device with a biased force: Upon loading the stabilization device will resist forces from the adjacent spine level with an higher force (corresponding to the upper stress plateau) than the stabilization device itself will develop to the adjacent spine level (corresponding to the lower stress plateau). The biased force phenomenon of NiTi based damping device is used to avoid any detrimental impact of the spine stabilizer to adjacent spine levels.

[0010] Figure 1 shows a systematic stress-strain curve of a shape memory alloy at a temperature T > Af where Af is the Austenite finish temperature. If Af < 37°C the material is fully austenitic at body temperature. Upon loading at low strains the austenitic material deforms firstly elastically, exhibiting a typical Hook-type straight line, known from conventional materials. At a certain stress (point A in figure 1) the stress-strain curve deviates from the straight line and merges into a plateau in which the stress increases only very little while the material exhibits large strains. This phenomenon is caused by the formation of Stress-Induced Martensite (SIM) and the material will exhibit large strains without any significant increase of stress until all the entire material is transformed from Austenite into Stress-Induced Martensite (point B in figure 1). Any loading beyond point D would first cause an elastic deformation of the Stress-Induced Martensite to

point E with a significant increase of stress and beyond that (not displayed in figure 1) cause a plastic deformation of the material prior to rupture. Upon unloading at point B the material will first release a portion of it's elastic stress and will at point D start to transform the martensitic microstructure back to Austenite following the lower plateau line until at point E the material is fully austenitic again. During this cycle very large deformations up to - 6 - 8 % strain (about 30 times those of conventional steel) can ideally be fully "elastically" recovered. This phenomenon is generally referred as Superelasticity or Pseudoelasticity.

[0011] During cycling through the superelastic stress-strain hysteresis and thus the formation of Stress-Induces Martensite and the formation of Austenite energy is dissipated.

[0012] The present invention uses this material phenomenon as a method and apparatus to absorb shocks in the human body. There are a number of advantages using this phenomenon for implantable damping elements in the human body:

First, shape memory alloys based on Nickel-Titanium (Nitinol) are biocompatible and already widely used for implants in the human body.

Secondly, the above materials exhibit the superlastic stress-strain hysteresis at body temperature.

Thirdly, compared to other damping methods for example the visco-elastic damping method (US 6582466) the force deflection hysteresis of a shape memory alloy can be utilized to build flexible implants of a simple construction with a damping capability not just in compression and tension, but also in flexion, extension as well as in rotation

Fourthly, the reliability of a damping apparatus build from a shape memory alloy is much higher compared to other known damping methods. The stress-strain hysteresis can be performed at indefinite numbers with a high fatigue life. This is of particular importance for an implant which will be in the human body for many years.

[0013] Another advantage of a shape memory alloy is that it's damping capacity can be changed by the material (chemical composition), grain size, microstructure, porosity and defect structure in the material. Even more importantly, the level of the stress plateaus depends on the ambient temperature. Accordingly it is possible to alter the stress-strain characteristics of a damping element out of a shape memory alloy by heating or cooling. Cooling or heating of the SMA elements would therefore result in an in-situ change of the plateau stresses.

Brief Description of the Drawings

[0014]

Fig. 1 shows the general stress-strain behaviour of a shape memory alloy on loading and unloading with distinctive stress plateaus.

Fig. 2 illustrates the schematic stress-strain behaviour of a damping element constructed out of a SMA tension and compression spring.

Fig. 3 illustrates the plan view of a damping element device built from a combined SMA tension and compression spring.

Fig. 4 illustrates the schematic stress-strain behaviour of a damping element constructed from a SMA compression spring.

Fig. 5 illustrates the plan view of a SMA damping element constructed from a compression spring

Fig. 6 shows a side view of two adjacent vertebrae with a SMA damping element space holder in between and a dynamic stabilization device based on SMA damping elements fixed by pedicle screws

Description of the preferred Embodiments

[0015] Figure 3 shows a damping element consisting out of a SMA tension and a compression spring. The upper spring is the compression spring, the lower spring is the tension spring. Both springs are pre-strained in order to assure that tension and compression occur only in the region of the plateaus. Figure 3a shows the damping element prior to any loading. In this condition the force of the compression spring correlates to the point O or O' on the stress strain curve in figure 2 depending on the loading or unloading condition. The tension element rests at point L (loading) or L' (unloading).

[0016] Upon the first tension of the damping element (Fig. 3b) the stress-strain behaviour of the tension spring follows the curve L'- L - M (figure 2). The transition from L' to L basically occurs with very little strain but a significant increase in stress (force). After reaching the stress of the superelastic loading plateau the spring strains to point M without any further significant increase of the stress (force). In case that no further tension occurs and the tension stress is released the tension spring follows the unloading cycle from M to M'and finally to L'. By doing so the energy dissipated within this loop corresponds to the area of the rectangular L'- L - M - M'.

[0017] The case of further tension (beyond point M in figure 4) is displayed in figure 3c: The tension spring is strained to point N (fig. 2) of the stress-strain curve. Any further tension beyond point N should be hampered, either by the natural increase of the stress beyond the load-

ing plateau stress or by constructive means of the spring elements. Upon relief of the stress the tension spring first follows the unloading plateau stress to point N'and thereafter the unloading plateau to those strains which correspond to the applied stress levels up to the point L'which defines the pre-strained tension of that spring.

[0018] It is important to point out that due to the hysteresis the SMA damping element will resist forces applied to it with an higher force (corresponding to the upper stress plateau) than it will develop to the human body (corresponding to the lower stress plateau).

[0019] Since the damping element consists out of a tension and a compression spring, damping (energy dissipation) occurs also in compression. Moderate compression is displayed in figure 3d while the tension spring is not activated. Upon compression the compression spring moves it's stress-strain characteristics from point O' to O and furthermore to point P (Figure 2). If the stress is released at this point the stress-strain characteristics will follow the line from P to P'and thereafter to strains corresponding stresses of the unloading up to the pre-strained condition (point O'). The damping (energy dissipation) corresponds to the area of the rectangular made between O'- O - P - P' (Figure 2). The case of a maximal compression of the compression spring is shown in figure 3e: In this case the spring is at maximum allowable strains corresponding to point Q (Figure 2). Any further compression is hampered either by the natural increase of the stress after the loading stress plateau or must be by constructive means of the spring element. If the compression is released the stress-strain behaviour follows the line from Q to Q' and thereafter the unloading plateau to strains corresponding to the remaining compression stresses. Again the amount of damping (energy dissipation) corresponds to the area build by the rectangular of the stress-strain hysteresis.

[0020] In one embodiment of the invention the damping device consists only out of a compression element Figure 5). The stress-strain behaviour of the compression element is displayed within the general stress-strain behaviour of a shape memory alloy in figure 4. The compression element is pre-strained to at least point O of the stress plateau. The pre-straining can occur by either constructive means (for example as indicated in figure 5a) or alternatively, by applying sufficient a force during application in the human body. During a compression cycle the damping behaviour (energy dissipation) is achieved by cycling the compression element within a rectangular within the points O - P - Q - Q'- P'- O'. The pre-strained damping element in figure 5a would be at point O' upon an unloading condition in figure 4. On compression the damping element develops a relatively high force F1 to reach the upper stress plateau (point O) before it will be significantly strained. Once the stress plateau is reached only very little additional stress (force) is needed in order to cause compression of the damping element. Full compression of the damping element is reached at point Q in figure 4, corresponding to figure 5b. Upon relief of the compressive force the stress-strain behavior of the damping element reduces it's compression following the unloading curve Q'- P'- O'. : It is important to note that - due to the stress-strain hysteresis - upon unloading a much lower force F2 from the compression element to the human body is developed compared to force F1 the compression element itself resists the compressive force. It is understood that the compression of the damping element beyond point Q will be avoided either by further increase of stress due to the elastic deformation of the Martensite or has to be done by constructive constraints.

[0021] It should also be mentioned that any pre-straining of the damping element can also be achieved by using the natural loads applied by the human body. In this case it can be of advantage to set the pre-strain to point P or P'of the stress-strain curve.

[0022] It is another embodiment of the invention to use the specific stress-strain characteristics of a NiTi based SMA alloy to provide non-linear resistance for dynamic stabilization of the spinal column. High stiffness for small strain levels due to the elastic deformation of the austenitic phase and a reduced stiffness for intermediate strain levels (loading/unloading plateau) provide a an ideal centering force for a dynamic stabilization device with an increased resistance in the central zone of the stabilizer (corresponding to the neutral zone of the spine) and much less resistance beyond the central zone of the stabilizer which is essential for a dynamic stabilization device (PANJABI, WO 04098452A2). In addition to that, the stress increase of NiTi based SMA's after the stress-plateaus due to the elastic deformation of the Martensite ca be used to provide a high resistance at the end of the range of motion.

[0023] Figure 6 shows an application of the first two embodiments of the invention, which is the application of a NiTi based SMA damping element as a space holder between two adjacent vertebrae and a dynamic stabilization device fixed by pedicle screws on the spinal column. The advantage of the SMA space holder which can also be constructed with an open structure to inject bone mass is in contrast to the prior art is that true damping is provided leading to less impact to adjacent spine levels. The same applies to the dynamic stabilization device which in addition will provide an ideal centring force and a stress-strain characteristic with an increase resistance in the central zone and less resistance beyond the central zone of the spine.

[0024] Briefly summarized, the present invention relates to a damping and shock absorbing method and apparatus for permanent or non-permanent use in the human body consists out of a shape memory alloy material which is cycled through the stress-strain hysteresis to dissipate energy for an effective damping. A sufficiently high pre-stress is applied to the damping element(s) to ensure that the damping working range is within the supererlastic cycle. The damping apparatus can be designed to work in tension or compression or - by combi-

nation of compression and tension elements - both in tension and compression. Moreover, damping elements from a shape memory alloy can be designed to work also in flexion and extension as well in rotation. The damping apparatus can be designed to have a stroke and force suitable for use in the human body by the design, the structure and the chemical composition of the shape memory alloy and their pre-set properties, such as plateau stresses and transformation temperature. Since plateau stresses of the superelastic cycle depend on the ambient temperature, the force of damping elements can also be changed in-situ by changing the temperature of the damping elements. The damping elements out of a shape memory alloy can be combined with elastic elements out of other materials to achieve stress-strain behaviour more suitable for use in the individual human body.

Claims

1. A damping apparatus for absorbing energy during dynamic loading in the human body comprising:

   at least one shape memory alloy damping element exhibiting a superelastic stress-strain behaviour at body temperature, wherein the damping element is pre-strained within the apparatus and adapted to achieve damping by cycling - at least partly - through the superelastic stress-strain cycle.

2. The apparatus of claim 1, wherein the shape memory alloy comprises a binary NiTi shape memory alloy (for example Ti-50.8at%Ni) or ternary NiTi shape memory alloy.

3. The apparatus of claim 1 or 2, wherein the damping element is produced by casting and heat treatment to overcome unsymmetrical response in compression vs. tension of cold worked NiTi materials.

4. The apparatus of any of claims 1 to 3, wherein the shape memory damping element comprises springs, particularly NiTi springs.

5. The apparatus of any of the preceding claims, wherein at least two damping elements are provided, one of which functioning as a compression spring and the other as a tension spring.

6. Dynamic stabilization device and intervertebral spacer element for the spinal column and for artificial joints such as hip implants, comprising the apparatus as defined in any of claims 1 to 5.

7. Use of shape memory alloy damping devices for dynamic stabilization devices and intervertebral spacer element for the spinal column and for artificial joints such as hip implants.

8. In-situ change of damping characteristics by changing the temperature of the SMA damping element.

9. A shape memory alloy self centring dynamic stabilization device with an increased resistance in the central zone of the stabilizer (corresponding to the neutral zone of the spine) and much less resistance beyond the central zone of the stabilizer.

10. A intervertebral spacer and dynamic stabilization device, respectively built from a shape memory alloy which will resist outside forces with an higher force (corresponding to the upper stress plateau) than it will itself develop to the adjacent spine level (corresponding to the lower stress plateau).

11. Method for absorbing energy during dynamic loading in the human body, comprising the step of providing at least one shape memory alloy damping element exhibiting a superelastic stress-strain behaviour at body temperature, wherein the damping element is pre-strained within the apparatus and adapted to achieve damping by cycling - at least partly - through the superelastic stress-strain cycle.

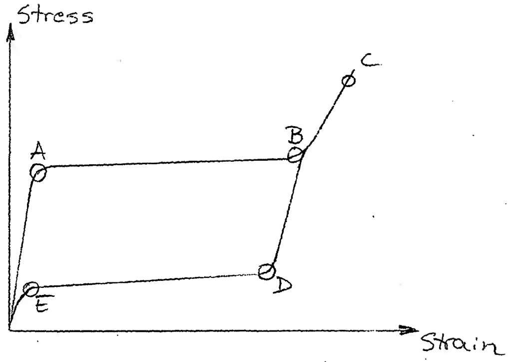

Fig. 1

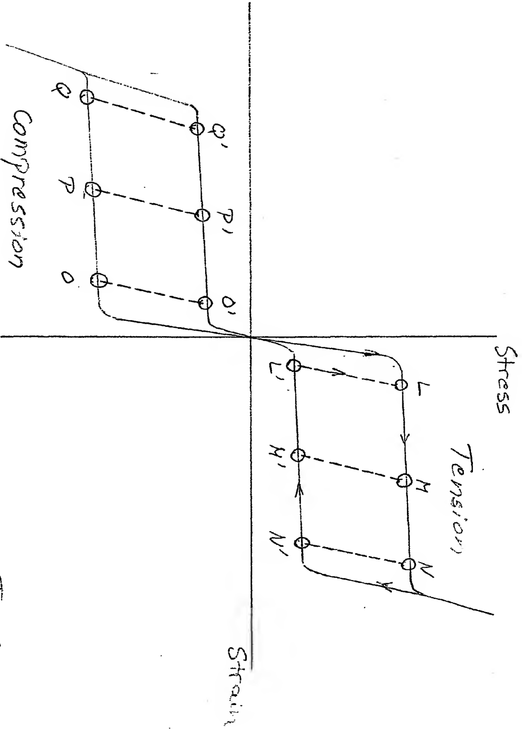

Fig. 2

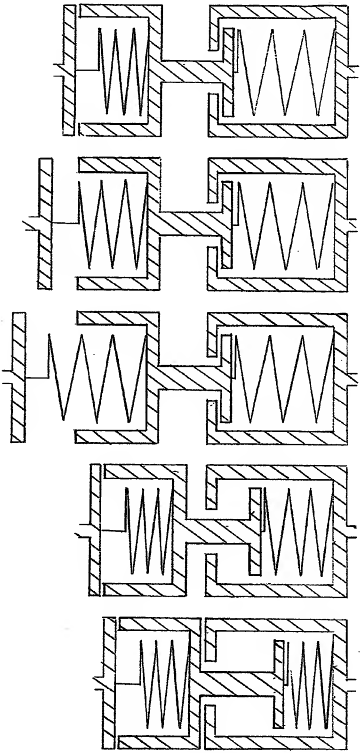

Fig. 3a

Fig. 3b

Fig. 3c

Fig. 3d

Fig. 3e

Fig. 3

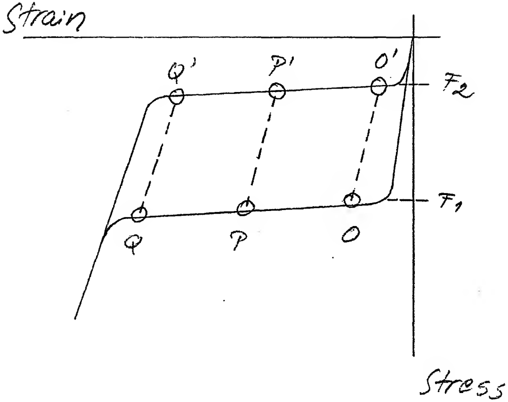

Fig. 4

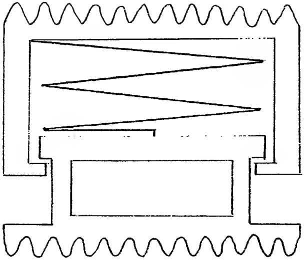

Fig. 5a

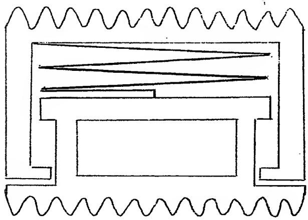

Fig. 5b

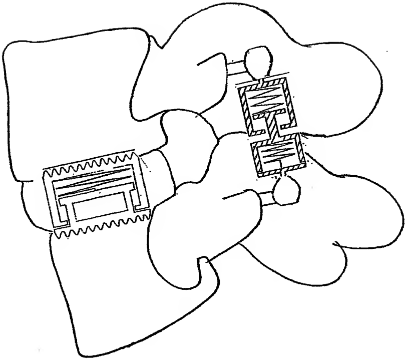

Fig 6

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EUROPEAN SEARCH REPORT

Application Number
EP 05 02 1542

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The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
Munich	11 August 2006	Pirog, P

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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A : technological background
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D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

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EPO FORM 1503 03.82 (P04C01)

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 05 02 1542

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Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
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The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
Munich	11 August 2006	Pirog, P

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EPO FORM 1503 03.82 (P04C01)

European Patent Office

Application Number
EP 05 02 1542

CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing more than ten claims.

☐ Only part of the claims have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims and for those claims for which claims fees have been paid, namely claim(s):

☐ No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims.

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

see sheet B

☒ All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.

☐ As all searchable claims could be searched without effort justifying an additional fee, the Search Division did not invite payment of any additional fee.

☐ Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid, namely claims:

☐ None of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims, namely claims:

European Patent Office

LACK OF UNITY OF INVENTION
SHEET B

Application Number
EP 05 02 1542

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. claims: 1-5,11

   Damping apparatus for absorbing energy during dynamic loading in the human body comprising at least one shape memory alloy damping element exhibiting a superelastic stress-strain behaviour at body temperature, wherein the damping element is pre-strained within the apparatus and adapted to achieve damping by cycling - at least partly - through the superelastic stress-strain cycle, wherein at least two damping elements are provided, one of which functioning as a compression spring and the other as a tension spring

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2. claims: 6-7,9-10

   Dynamic stabilzation device and intervertebral spacer for the spinal column.

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3. claim: 8

   In-situ change of damping characteristics by changing the temperature of the SMA damping element.

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 05 02 1542

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
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